

Claims

What is claimed is:

- 1 1. A kit for the isolation and subsequent qualitative or quantitative characterization
2 of target biomolecules present in biological fluid comprising: at least one MSIA-
3 Tip having an affinity reagent present within the tip, at least one internal reference
4 standard of predetermined concentration, and at least one mass spectrometer
5 target.
- 1 2. The kit according to claim 1 wherein the affinity reagent further comprises an
2 affinity ligand, said affinity ligand further comprises anti-human β -2-
3 microglobulin antibody.
- 1 3. The kit according to claim 1 wherein the internal reference standard is an internal
2 reference standard that shares sequence homology with the target biomolecule.
- 1 4. The kit according to claim 3 wherein the internal reference standard that shares
2 sequence homology with the target biomolecule is selected from the group
3 comprising enzymatic/chemically-modified versions of the target biomolecule,
4 truncated/extended recombinant forms of the target biomolecules, the target
5 biomolecule recombinantly expressed in isotopically-enriched media, and the
6 target biomolecule from a different biological species.
- 1 5. The kit according to claim 3 wherein the internal reference standard that shares
2 sequence homology with the target biomolecule is equine β -2-microglobulin.

1 6. The kit according to claim 2 wherein the internal reference standard is an internal
2 reference standard that shares sequence homology with the target biomolecule.

7. The kit according to claim 6 wherein the internal reference standard that shares sequence homology with the target biomolecule is selected from the group comprising enzymatic/chemically-modified versions of the target biomolecule, truncated/extended recombinant forms of the target biomolecules, the target biomolecule recombinantly expressed in isotopically-enriched media, and the target biomolecule from a different biological species.

1 8. The kit according to claim 6 wherein the internal reference standard that shares
2 sequence homology with the target biomolecule is equine β -2-microglobulin.

1 9. A method for the isolation and subsequent qualitative characterization of target
2 biomolecules present in biological fluid comprising the steps of:

- 3 a. providing a MSIA-Tip having an affinity reagent present,
- 4 b. separating and concentration the target biomolecule directly from the
5 biological fluid by flowing a volume of the biological fluid through the
6 MSIA-Tip, thereby binding the target biomolecules to the affinity reagent,
- 7 c. eluting the target biomolecules onto a mass spectrometer target,
- 8 d. performing mass spectrometric analysis on the target biomolecules in
9 order to qualitatively determine the presence or absence of the target
10 biomolecule in the biological fluid.

- 1 10. The method according to claim 9 wherein the affinity reagent further comprises
2 an affinity ligand, said affinity ligand further comprises anti-human β 2-
3 microglobulin antibody.
- 1 11. The method according to claim 9 wherein the qualitative determination further
2 determines the presence of mass shifted variants of the target biomolecule.
- 1 12. The method according to claim 10 wherein the qualitative determination further
2 determines the presence of mass shifted variants of the target biomolecule.
- 1 13. A method for the isolation and subsequent quantitative characterization of target
2 biomolecules present in biological fluid comprising the steps of:
3 a. adding a known amount of internal reference standard of predetermined
4 concentration to a sample of the biological fluid,
5 b. providing a MSIA-Tip having an affinity reagent present,
6 c. flowing a volume of the biological fluid through the pipettor tip, thereby
7 binding the target biomolecules to the affinity reagent,
8 d. eluting the target biomolecules to a mass spectrometer target,
9 e. performing mass spectrometric analysis on the target biomolecules in
10 order to quantitatively determine the concentration of the target
11 biomolecule in the biological fluid.

1 14. The method according to claim 13 wherein the affinity reagent further comprises
2 an affinity ligand, said affinity ligand further comprises anti-human β -2-
3 microglobulin antibody.

1 15. The method according to claim 13 wherein the internal reference standard is an
2 internal reference standard that shares sequence homology with the target
3 biomolecule.

1 16. The method according to claim 15 wherein the internal reference standard that
2 shares sequence homology with the target biomolecule is selected from the group
3 comprising enzymatic/chemically-modified versions of the target biomolecule,
4 truncated/extended recombinant forms of the target biomolecules, the target
5 biomolecule recombinantly expressed in isotopically-enriched media, and the
6 target biomolecule from a different biological species.

1 17. The method according to claim 15 wherein the internal reference standard that
2 shares sequence homology with the target biomolecule is equine β -2-
3 microglobulin.

1 18. The method according to claim 14 wherein the internal reference standard is an
2 internal reference standard that shares sequence homology with the target
3 biomolecule.

1 19. The method according to claim 18 wherein the internal reference standard that
2 shares sequence homology with the target biomolecule is selected from the group
3 comprising enzymatic/chemically-modified versions of the target biomolecule,
4 truncated/extended recombinant forms of the target biomolecules, the target
5 biomolecule recombinantly expressed in isotopically-enriched media, and the
6 target biomolecule from a different biological species.

1 20. The method according to claim 18 wherein the internal reference standard that
2 shares sequence homology with the target biomolecule is equine β 2-
3 microglobulin.

21. The method according to claim 13 wherein the quantitative determination further determines the concentration of mass shifted variants of the target biomolecule.

22. The method according to claim 14 wherein the quantitative determination further determines the concentration of mass shifted variants of the target biomolecule.

23. The method according to claim 15 wherein the quantitative determination further determines the concentration of mass shifted variants of the target biomolecule.

24. The method according to claim 16 wherein the quantitative determination further determines the concentration of mass shifted variants of the target biomolecule.

25. The method according to claim 17 wherein the quantitative determination further determines the concentration of mass shifted variants of the target biomolecule.

1 26. The method according to claim 18 wherein the quantitative determination further
2 determines the concentration of mass shifted variants of the target biomolecule.

1 27. The method according to claim 19 wherein the quantitative determination further
2 determines the concentration of mass shifted variants of the target biomolecule.

1 28. The method according to claim 20 wherein the quantitative determination further
2 determines the concentration of mass shifted variants of the target biomolecule.

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